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Subject:	COMMISSION REGULATION (EU) .../... of XXX refusing to authorise a health claim made on foods and referring to children's development and health

Delegations will find attached document D044670/02.

Encl.: D044670/02



Brussels, **XXX**
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(POOL/E1/2015/12498/12498-EN.doc)
D044670/02
[...](2016) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**refusing to authorise a health claim made on foods and referring to children's
development and health**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

refusing to authorise a health claim made on foods and referring to children's development and health

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods¹, and in particular Article 17(3) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.
- (3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Vifor Ltd, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Equazen eye q[®] and improving reading ability (Question No EFSA-Q-2014- 00462²). The claim proposed by the applicant was worded as follows: "Equazen eye q[®] (composition of EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability and related cognitive functions in children".

¹ OJ L 404, 30.12.2006, p. 9.

² EFSA Journal 2015;13(10):4251.

- (6) On 13 October 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER